

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Group Art Unit: 1616
CHANTAL AMALRIC et al Examiner: M. Lamm

Serial No.: 10/635,898

Filed: August 7, 2003

For: NOVEL TOPICAL COMPOSITIONS WITH AN OILY OUTER PHASE AND
PROCESS FOR THEIR PREPARATION

SUPPLEMENTAL DECLARATION OF CHANTAL AMALRIC UNDER 37 CFR § 1.132

Honorable Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Chantal AMALRIC, do hereby declare as follows:

I am a named inventor of the above-identified patent application, and am employed by SEPPIC, the assignee of the application.

CA As reported in my previous Declaration under 37 CFR 1.132, we found in tests carried out in our laboratories and under my supervision, that only gelifying polymers within the group now recited in the independent claims of the present application allow, with emulsions according to the invention, water-in-oil emulsions (not oil-in-water emulsions) to be obtained which are stable over time despite the use of minimal amounts of (external) oil phase compared to the (internal) aqueous phase.

The chosen group of polymers did therefore provide "unexpected results," going beyond the simple thickening role which could have been expected of them from the prior art, namely they stabilize particular types of emulsion in which the oil phase remains the external phase (within which aqueous droplets are dispersed) despite constituting less than 20% (even as little as 10%) of the overall emulsion.

The compositions found to be stable with small amounts of oil as the external phase contained 10% and 15% by weight oil in the external phase.

Further experiments were carried out to show that similar results can be obtained within a range of 2 to 20% by weight oil in the external phase.

General method of preparation of emulsions

- 1) The oil(s) and (lipophilic) emulsifier(s) of phase A are mixed in a beaker, using a mechanical stirrer with an "anchor"-type rotor at moderate speed (approximately 100 rpm);
- 2) Phase B is prepared by adding glycerin and magnesium sulphate to water contained in another beaker while stirring at moderate speed (approximately 100 rpm);
- 3) Phase B is added to phase A while maintaining stirring at 400 rpm and heating to 70 to 80°C;
- 4) The mixture is then stirred using a stirring device equipped with a rotor-stator, at a shearing speed of 8000 rpm, for a period of 8 minutes with a quantity of material of 200 g, in order to obtain a homogeneous emulsion;
- 5) In a third beaker, the thickening polymer is dispersed in water to give rise to phase C, while stirring with a deflocculating blade at room temperature, in order to give an aqueous gel;

- 6) The ingredients of phase D, which include sunscreen filter agents, are added to the aqueous gel formed in step 5), while stirring the mixture using a deflocculating blade;
- 7) The homogeneous emulsion, obtained in step 4) by mixing phase B and phase A, is added to the mixture of (aqueous gel phase C + sunscreen filter-containing phase D) prepared in step 6), whilst using moderate stirring, using an "anchor"-type rotor, at a speed of 300 rpm. Stirring of this mixture is continued until a fully homogeneous mixture is obtained.

The following compositions, containing 4%, 12% and 18% by weight oil in the external phase were obtained:

Formulation with 4% by weight of oil

Component	% by weight
Phase A (oil and emulsifier)	
Dimethicone DC 200 (350) ¹	2.00
C12-C15 alkylbenzoate ²	2.00
PEG30-dipolyhydroxystearate ³	0.60
Octyldodecanol / Octyldodecyl xyloside ⁴	2.40
Phase B (aqueous phase of "primary" emulsion)	
Magnesium sulfate, 7H ₂ O	0.01
Glycerin	1.00
Water	5.00
Phase C (gelified aqueous phase)	
Hydroxyethyl acrylate & Sodium acryloyldimethyl taurate copolymer ⁵	0.80
Water	qs 100
Phase D (contains sunscreen filter agents)	
Homomenthyl salicylate (homosalate) ⁶	8.00
Octylmethoxycinnamate (octinoxate) ⁷	6.00
Preservative	qs
Perfume	qs

- ¹ Obtained from DOW CORNING
- ² Obtained from STEARINERIE DUBOIS
- ³ Obtained from SEPPIC (the mixture of PEG-30 dipolyhydroxystearate with the octyldodecanol / octyldodecyl xyloside mixture (the latter being sold as FLUIDANOV® 20X), is sold by SEPPIC under the brand name EASYNOV®)
- ⁴ Obtained from SEPPIC (sold under brand name FLUIDANOV® 20X)
- ⁵ Obtained from SEPPIC (sold under brand name SEPINOV® EMT 10)
- ⁶ Obtained from HAARMAN & REIMER (sold under brand name NEOHELIOPAN® HMS)
- ⁷ Obtained from ISP (sold under brand name ESCALOL® 557)

When an emulsion is prepared using these components according to the general method of preparation set out above, a water-in-oil emulsion stable for at least one month is obtained.

Formulation with 12% by weight of oil

<u>Component</u>	<u>% by weight</u>
Phase A (oil and emulsifier)	
Caprylic capric triglyceride ¹	12.00
Octyldodecanol / Octyldodecyl xyloside ²	2.40
PEG45 dodecylglycol copolymer ³	0.60
Titanium dioxide ⁴	3.00
Zinc oxide ⁵	3.00
Phase B (aqueous phase of "primary" emulsion)	
Magnesium sulfate, 7H ₂ O	0.02
Glycerin	1.50
Water	9.00
Phase C (gelified aqueous phase)	
Hydroxyethyl acrylate & Sodium acryloyldimethyl taurate copolymer with Isohexadecane and Polysorbate 80 ⁶	2.10
Water	qs 100
Phase D (contains sunscreen filter agents)	
Ethyl hexyl salicylate (octisalate) ⁷	3.50
Octylmethoxycinnamate (octinoxate) ⁸	5.25
Preservative	qs
Perfume	qs

- ¹ Obtained from STEARINERIE DUBOIS (sold under brand name DUB 5545)
- ² Obtained from SEPPIC (sold under brand name FLUIDANOV® 20X)
- ³ Obtained from AKZO (sold under brand name ELFACOS® ST9)
- ⁴ Obtained from SUNSMART (sold under brand name MT100T)
- ⁵ Obtained from TAYCA (sold under brand name Z COTE® HP1)
- ⁶ Obtained from SEPPIC (sold under brand name SIMULGEL® EG)
- ⁷ Obtained from MERCK (sold under brand name EUSOLEX® OD)

⁸ Obtained from ISP (sold under brand name ESCALOL® 557)

When an emulsion is prepared using these components according to the general method of preparation set out above, a water-in-oil emulsion stable for at least one month is obtained.

Formulation with 18% by weight of oil

Component	% by weight
Phase A (oil and emulsifier)	
Diisopropyl adipate ¹	18.00
Octyldodecanol / Octyldodecyl xyloside ²	2.40
PEG30-dipolyhydroxystearate ³	0.60
Titanium dioxide ⁴	10.00
Phase B (aqueous phase of "primary" emulsion)	
Magnesium sulfate, 7H ₂ O	0.04
Glycerin	1.50
Water	20.00
Phase C (gelified aqueous phase)	
Hydroxyethylacrylate/sodium acryloyldimethyl taurate copolymer with squalane and polysorbate 60 ⁵	2.20
Water	qs 100
Phase D (contains sunscreen filter agents)	
2-Ethylhexyl-2-cyano-3,3-Diphenylacrylate (Octocrylene) ⁶	6.00
Preservative	qs
Perfume	qs

¹ Obtained from STEARINERIE DUBOIS (sold under brand name DUB DIPA)

² Obtained from SEPPIC (sold under brand name FLUIDANOV® 20X)

³ Obtained from SEPPIC (the mixture of PEG-30 dipolyhydroxystearate with the octyldodecanol / octyldodecyl xyloside mixture (the latter being sold as FLUIDANOV® 20X), is sold by SEPPIC under the brand name EASYNNOV®)

⁴ Obtained from SUNSMART (sold under brand name MT100T)

⁵ Obtained from SEPPIC (sold under brand name SIMULGEL® NS)

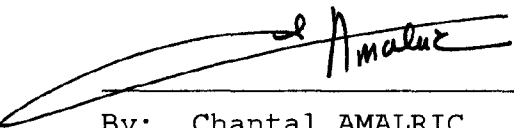
⁵ Obtained from SEPPIC (sold under brand name SEPINOVO® EMT 10)

⁶ Obtained from ISP (sold under brand name ESCALOL® 597)

When an emulsion is prepared using these components according to the general method of preparation set out above, a water-in-oil emulsion stable for at least one month is obtained.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

OCT. 17th 2006
Date


By: Chantal AMALRIC